October 7, 2022

DOC Brands, Inc.
Eric Mowell
Vice President Marketing and Product Development
407 E. Lancaster Avenue
Wayne, Pennsylvania 19087

Re: K222424
Trade/Device Name: Protect-It Custom Fit Dental Guard
Regulatory Class: Unclassified
Product Code: OBR
Dated: August 11, 2022
Received: August 11, 2022

Dear Eric Mowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222424

Device Name

Protect-It Custom Fit Dental Guard

Indications for Use *(Describe)*

Protect-It Custom Fit Dental Guard is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to teeth associated with bruxing or nighttime teeth grinding.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5: 510(k) SUMMARY

DOC Brands, Inc.'s Protect-It Custom Fit Dental Guard (K222424)

510(k)'s Owner's Name, Address, Phone Number:
DOC Brands, Inc.
407 E. Lancaster Avenue
Wayne, PA 19087
Phone: 833-362-2763

Contact Person and Date Prepared:
Eric Mowell
DOC Brands, Inc., VP Marketing and Product Development
Date: August 10, 2022

Subject Device
Device Trade Name: Protect-It Custom Fit Dental Guard
Device Common or Usual Name: dental guard, nightguard
Classification Name: Mouthguard, Over-the-Counter
Regulation Number: N/A
Product Code and Class: OBR; unclassified
Classification Panel: Center for Devices and Radiological Health; Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices

Predicate Device
Trade Name: Ready-Fit Disposable Dental Guard
Applicant: DenTek Oral Care, Inc.
Classification Name: Mouthguard, Over-the-Counter
Regulation Number: N/A
Product Code and Class: OBR; unclassified
510(k) Number: K151149

Reference Device – used in device equivalence comparison
Trade Name: Custom Comfort Nightguard Version 2
Applicant: DenTek Oral Care, Inc.
Classification Name: Mouthguard, Over-the-Counter
Regulation Number: N/A
Product Code and Class: OBR; unclassified
510(k) Number: K091660
Current Marketed Name: DenTek Professional Fit Dental Guard

Reference Device – used to substantiate after-market biological performance of EVA material
Trade Name: Ora-GUARD Dental Grind Guard
Applicant: Bite Tech Inc.
Classification Name: Mouthguard, Over-the-Counter
Regulation Number: N/A

SECTION 5: 510(k) SUMMARY

Product Code and Class: OBR; unclassified
510(k) Number: K150492

Subject Device Description

Protect-It Custom Fit Dental Guard is an over-the-counter device to be used by lay people for protection against the effects of nighttime teeth grinding. It is made of a single thermoplastic resin, ethylene vinyl acetate copolymer, EVA, which is easily molded to the teeth when heated. It is a full-occlusal guard worn on the upper teeth, providing a cushion to separate the upper and lower teeth and keep them apart while sleeping, thus reducing the damage to teeth associated with bruxism.

Indications For Use/Intended Use

The subject device, Protect-It Custom Fit Dental Guard, is an over-the-counter device, indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to teeth associated with bruxing or nighttime teeth grinding.

The predicate device, DenTek's Ready-Fit Disposable Dental Guard, is an over-the-counter device and has the exact same indication for use and intended use as the subject device. The predicate is indicated for protection for nighttime teeth grinding or bruxism. It is intended to reduce damage to teeth by cushioning them and keeping them apart during grinding.

Technological Characteristics

The subject device, Protect-It Custom Fit Dental Guard is a full occlusal, dental guard made of a single thermoplastic resin, ethylene/vinyl acetate copolymer (EVA), which forms easily to the teeth when heated. By design, it effectively cushions the teeth and keeps them apart during sleep, thus reducing the damage to teeth associate with nighttime teeth grinding. The heat and form process is a commonly used method for fitting full occlusal mouth guards. The referenced device, DenTek's Custom Comfort Dental Guard Version 2 (K091660) is an example of a guard of similar design (shape and size) that is a heat and form dental guard.

The predicate device, DenTek's Ready-Fit Disposable Dental Guard, is a posterior-occlusive mouth-guard, consisting of two bite pads made of a single thermoplastic resin, ethylene/methyl acrylate copolymer (EMA), which are connected by a buccal band that aids in fit and retention. The predicate is a ready to wear, one size fits all design. It has the same intended use as the subject device, to reduce damage to teeth by cushioning them and keeping them apart during nighttime teeth grinding. Thus, the subject device and the predicate device have the exact same technological operating principles. The technological/design differences between Protect-It Custom Fit Dental Guard and the predicate, Ready-Fit Disposable Dental Guard, are minor and do not raise any new questions of safety or effectiveness. Therefore, the subject device is technologically

equivalent to the predicate device. Both the subject device and the predicate device are indicated for over-the-counter use, for age 18 and over.

Substantial Equivalence Discussion

The following table compares the Protect-It Custom Fit Dental Guard to the predicate device with respect to intended use and technological characteristics. It demonstrates the basis for the determination of substantial equivalence. The addition of the reference device comparison presents another substantially equivalent dental guard that is on the market today.
Any minor differences are explained in the narrative below the table.

DOC Brands, Inc. Protect-It Custom Fit Dental Guard vs DenTek Oral Care Inc.'s Ready-Fit Disposable Dental Guard - K151149

	Subject Device Protect-It Custom Fit Dental Guard (K222424)	**Predicate Device** Ready-Fit Disposable Dental Guard (K151149)	**Reference Device** Custom Comfort Nightguard Version 2 (K091660)	**Differences**
Manufacturer	DOC Brands, Inc.	DenTek Oral Care, Inc.	DenTek Oral Care, Inc.	
510(k) #	K222424	K151149	K091660	
Device Classification Name	Mouthguard, Over-the-Counter	Mouthguard, Over-the-Counter	Mouthguard, Over-the Counter	NONE
Regulation #	None Applicable	None Applicable	None Applicable	NONE
Product Code	OBR	OBR	OBR	NONE
Regulatory Class	Not Classified	Not Classified	Not Classified	NONE
Device Description	Full-occlusion, single material, injection molded one-shot, heat and form moldable material.	Partial-occlusion, single material, injection molded one-shot, bite tubes connected by buccal band, ready to wear.	Full-occlusion, two materials, injection molded – two shot; hard base with moldable heat and form material in top layer. Formed using the provided fitting tray.	Specific design differences are addressed further below.
Packaging Content	Package contains 4 dental guards and one storage case. IFU on outer carton.	Package contains 12 or 16 disposable dental guards. No IFU needed.	Package contains 1 dental guard, 1 disposable fitting tray, one storage case and IFU.	No performance impact.

SECTION 5: 510(k) SUMMARY

DESIGN	Subject Device Protect-It Custom Fit Dental Guard (K222424)	Predicate Device Ready-Fit Disposable Dental Guard (K151149)	Reference Device Custom Comfort Nightguard Version 2 (K091660)	Differences
Indications for Use and Intended Use	Protect-It Custom Fit Dental Guard is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to teeth associated with bruxing or nighttime teeth grinding.	Ready-Fit Disposable Dental Guard is indicated for protection for nighttime teeth grinding or bruxism. It is intended to reduce damage to teeth by cushioning them and keeping them apart during grinding.	Custom Comfort Nightguard Version 2 is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.	NONE
OTC or RX	OTC	OTC	OTC	NONE
User Population	Age 18 and up	Age 18 and up	Age 18 and up	NONE
Technological Characteristics	Flexible guard used as a barrier or cushion between upper and lower teeth.	Flexible guard used as a barrier or cushion between upper and lower teeth.	Flexible guard used as a barrier or cushion between upper and lower teeth.	NONE
Duration of Use	Reusable	Disposable after one night	6 month wear guarantee	[1]Minor (IHUT conducted to confirm reusable - see Section 18: Bench Testing). Subject device has no wear guarantee.
Materials	Comprised completely of moldable thermo-plastic resin - EVA (ethylene/vinyl acetate copolymer) **Taisox 7350 M**	Comprised completely of thermo-plastic resin, EMA (ethylene/methyl acrylate copolymer) **Elvaloy 1609 AC**	1st shot Base made of thermo-plastic resin (EMA) **Elvaloy 1609;** ---------- 2nd shot Upper moldable layer made of EVA - **Elvax 150**	[2]Minor (biocompatibility testing confirms the EVA resin of the subject device is appropriate for its intended use)
Tensile Strength at Break	14.71 MPa	13.0 MPa	13.0 MPa ---------- 7.6 MPa	
Tensile Strength at Yield	4.41 MPa	80 MPa	81 MPa ---------- 10.0 MPa	
Elongation at Break	800 %	740 %	740 % ---------- 1000 %	
Hardness Shore A	88	97	97 ---------- 65	
Hardness Shore D	38	46	46 ---------- 24	

SECTION 5: 510(k) SUMMARY

DESIGN	Subject Device Protect-It Custom Fit Dental Guard (K222424)	Predicate Device Ready-Fit Disposable Dental Guard (K151149)	Reference Device Custom Comfort Nightguard Version 2 (K091660)	Differences
Materials (cont.)	**Taisox 7350 M**	**EMA - Elvaloy 1609 AC**	**EMA – Elvaloy 1609** **----------** **EVA – Elvax 150**	
Melt Index	2.5 g/10 min	6.0 g/10 min	6.0 g/10 min ---------- 43 g/10 min	
Density	0.938 g/cm^3	0.93 g/cm^3	0.93 g/cm^3 ---------- 0.957 g/cm^3	
Fit	Full occlusion, heat and form for custom fit, worn on upper teeth. Excess length or wall height may be trimmed by user for one size fits all compatibility.	Posterior occlusion, ready-to-wear, one size fits all, worn on upper or lower teeth	Full occlusion, heat and form with forming tray for custom fit. Worn on upper teeth. Excess length of arch may be trimmed by user.	[3]Minor (full occlusion, heat and form design is similar to the reference device)
Dimensions (l x w x h)	5.25cm L x 6.614cm W x 1.814cm H	3.8cm L x 3.9cm W x 1.9cm H	3.8cm L x 6.3cm W x 0.9cm	[4]Minor (subject is similar to the predicate and reference devices)
Weight	0.3 ounce (10 grams)	0.04 ounce (1.33 grams)	0.2 ounce (6 grams)	[5]Minor (full occlusal vs partial occlusal accounts for weight differential in subject vs predicate)
Sterilization	Device is not sold sterile	Device is not sold sterile	Device is not sold sterile	NONE
Method of cleaning	Before fitting, wash in warm water and try on; wash in warm water after each use and store in case provided.	Disposable, no instructions for cleaning included	Brush with toothpaste or mouthwash and rinse in cool water after each use.	[6]Similar to reference device

The table above identifies a few minor differences between the proposed device and the cited predicate and referenced device. **1.** The specific durations of use per the products' labeling differ. However, the duration of use does not affect the safety or effectiveness of the subject device. Protect-It Custom Fit Dental Guard was verified to be reusable in a home use simulation (bench test), the report for which is provided in this submission (Section 18: Bench Testing). The longevity of the device will depend on the force of the grinding of the user. No wear guarantee is provided. **2.** While the contact material for the subject and predicate devices is a single ethylene-based copolymer, the exact resins are not identical. The subject device uses a similar EVA material as in the moldable layer of the reference device. The appropriateness of the

subject device's resin for use in a dental guard was demonstrated through bio-compatibility testing of the finished guard, which is provided in this application. See Section 15: Biocompatibility and Attachments 6-9, Biocompatibility test reports (four tests). **3.** The predicate utilizes a ready-to-wear, posterior-occlusion design whereas the subject device, like the reference device, utilizes a full-occlusion design, fit with the heat and form process. All are effective for the intended use. **4.** The measurements of the subject device differ from the predicate due to the overall design. The bite radius of the subject device is wider than the predicate because the predicate has a narrow strap between the bite pads that does not retain its in-use shape. The subject is longer as it is designed to be trimmed if needed by the user. Though not identical, the width measurement of the subject device is similar to the cited reference device. **5.** The subject device has a higher overall weight due to the full occlusal design versus the posterior-occlusal design of the predicate. The weight of the subject device and the reference device are similar. **6.** The subject device and reference device have similar instructions for inspecting and cleaning after each use.

The subject device and the predicate device have the same indications for use and intended use, the same user population and the same technological characteristics.

The minor differences between the subject device and the cited predicate do not raise different questions of safety or effectiveness and this application establishes that the subject device is as safe and effective as the predicate. Thus, the subject device, Protect-It Custom Fit Dental Guard is substantially equivalent to the predicate device, Ready-Fit Disposable Dental Guard. The addition of the reference device comparison presents another substantially equivalent dental guard that is on the market today.

In summary, although they fit the mouth in a slightly different manner, the subject device and the predicate device have the same technological characteristics and intended use, to protect the teeth from the damage of night-time grinding by cushioning them and keeping them apart.

In accordance with section 513(i)(1)(A) of the FDCA, a device is substantially equivalent (SE) when it has the same intended use and technological characteristics as a legally marketed predicate device. As demonstrated in this traditional 510(k), any differences between the subject device and the cited predicate do not raise different questions of safety or effectiveness and this application establishes that the device is as safe and effective as the predicate.

Non-Clinical Performance Testing

Bench Testing

DOC Brands, Inc. conducted an in-home use test (IHUT) which validated that the design of Protect-It Custom Fit Dental Guard meets the intended use and performance expectations of the device. See Section 18: Bench Testing, Attachment 4A: Bench Test Protocol, 4B: Bench Test Engineering Study, and Attachment 4C: Bench Test Data.

This data supports the subject's substantial equivalence to the predicate.

Biocompatibility Testing
Additionally, the following biocompatibility tests were performed on the subject device.

- In-vitro Cytotoxicity according to ISO 10993-5:2009(E). Results showed the tested device, the cited subject device, is non-cytotoxic.
- Skin Sensitization according to ISO 10993-10:2021(E). Results showed the tested device, the cited subject device, is a non-sensitizer.
- Intracutaneous Reactivity according to ISO 10993-23:2021(E). Results showed the tested device, the cited subject device, was non-reactive under the conditions of the study.
- Oral Mucosa Irritation according to ISO 10993-23:2021(E). Results showed the tested device, the cited subject device, was a non-irritant under the conditions of the study.

These tests further demonstrate the subject device's substantial equivalence to the cleared predicate device.

Conclusion

The Protect-It Custom Fit Dental Guard has the same indications for use and intended use, and the same technological characteristics and principles of operation as the predicate device, Ready-Fit Disposable Dental Guard. The relevant information on biocompatibility and the performance testing, confirm that the Protect-It Custom Fit Dental Guard fulfills its intended use as safely and effectively as the legally marketed predicate device. The Protect-It Custom Fit Dental Guard, the subject device, is therefore substantially equivalent to the predicate device, Ready-Fit Disposable Dental Guard.